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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089.521

08/23/2002

Mikael Simons

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08/01/2006

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/089,521

Applicant(s)

SIMONS ET AL.

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

The Amendment filed April 25, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 45-52 have been added

Claims 1-44 have been canceled.

Remarks drawn to rejections of Office Action mailed January 27, 2006 include:

112 2<sup>nd</sup> paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

112 1<sup>st</sup> paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

An action on the merits of claims 45-52 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Franklin et al. (Us 6,017,557).

Claim 45 is drawn to methods of modulating the sphingolipid-cholesterol microdomain in a patient in need of such modulation comprising optionally administering cholesterol sulfate to the patient in an amount effective to increase the detergent solubility of proteins associated with the domain. Claim 46 is drawn to a method of influencing the location of components associated with the domains using the same methods. Dependent claims limit the components to proteins, and various specific proteins. Dependent claims also limit the amount of cholesterol sulfate to 3-30 mg/kg body weight/day. Claim 52 provides the compound is cholesterol sulfate.

Franklin et al. disclose methods of treating cancer with a composition comprising cholesterol sulfate (see claim 8, for example). It is noted that while Franklin is silent to the effect of cholesterol sulfate on sphingolipid-cholesterol microdomains, Franklin must have inherently performed the methods as instantly claimed, as they administered the same compounds, in the same amounts, to the same patients, and therefor must have achieved the same results.

Franklin et al.'s methodological step of administering cholesterol sulfate would have inherently performed the method as instantly claimed. It is noted that if Franklin et al., having taken the manipulative steps described therein, had attempted to measure for the results as described in the instant application, Franklin et al. would have uncovered those results, as they are directly correlative to the method as practiced by Franklin et al. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using cholesterol sulfate containing compositions to treat

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cancer, as the prior arts method would have inherently performed the method as instantly claimed. See Ex Parte Novitski, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle. Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. EMI v. Cypress Semiconductor, 2001 US Fed. Cir. Ct. of App. In the instant case, the prior art teaches to treat cancer with cholesterol sulfate, and applicants recognize that their methods can be used in the control of tumors (see page 9-10 of specification). The art teaches to use a dosage of from 1-1000 mg/kg body weight (see column 9, lines 55-57). The instant claims require administering cholesterol sulfate, to a patient in need thereof, in an effective amount. Franklin et al's teaching of administering cholesterol sulfate, to a patient in need thereof, in overlapping amounts, would have necessarily performed the features as instantly claimed, as it is a direct result of the compound administered.

### ***Conclusion***

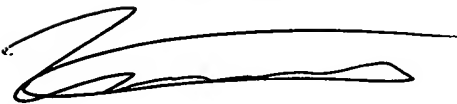
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III  
July 22, 2006



Shaojia A. Jiang  
Supervisory Patent Examiner  
Art Unit 1623

